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MCRVT-054A

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**FACSIMILE COVER SHEET**

Date: October 2, 2006

To: Commissioner for Patents  
Alexandria, VA 22313-1450

Facsimile: (571) 273-8300

Re: U.S. Patent Application No. 10/780,921  
Filing Date: 02/17/2004  
Title: "Alpha-Difluoromethylornithine (DFMO) Suppresses Polyamine  
Levels in the Human Prostate"  
Inventor(s): Meyskens et al.

From: Robert D. Buyan

Total No. of Pages: 6 (including this form). Please notify us immediately if you have not received all  
pages.

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Attached: Transmittal Letter (2 pgs.)  
Response to Restriction Requirement (3 pgs.)

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Atty. Docket No. UCIVN-058C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Meyskens )

Art Unit: 1614

Application No.: 10/780,921 )

Examiner: Anderson, James D.

Filed: 02/17/2004 )

For: Alpha-Difluoromethylornithine  
(DFMO) Suppresses Polyamine  
Levels in the Human Prostate )

**CERTIFICATE OF TRANSMISSION/MAILING**  
I hereby certify that this document is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents, Alexandria, VA 22313-1450 on October 2, 2006.

By:

Nancy V. McElrath

Transmittal Letter

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

☒ In accordance with Rule 136, the Commissioner is hereby petitioned for a three month-extension of time, extending to October 2, 2006 the period for response to the Office Action dated June 2, 2006. Please charge Deposit Account No. 50-0878 the amount of \$510 for the third month extension fee.

☐ Enclosed is a certified copy of Serial No. \_\_\_\_\_ from which priority is claimed in the subject case pursuant to 37 CFR § 1.55b and 35 U.S.C. §119.

☐ Enclosed is an Assignment of the invention to [Assignee], including a cover sheet and Check No. [Assignment Check No.] for \$40.

☐ A Declaration of Inventorship and Limited Power of Attorney is enclosed.

☐ A Certificate of Ownership and Power of Attorney is enclosed.

☒ Enclosed herewith is an amendment/response for filing in relation to the above-identified application. Entry and consideration of this amendment/response is requested.

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App. No.: 10/780,921  
Transmittal Letter  
October 2, 2006

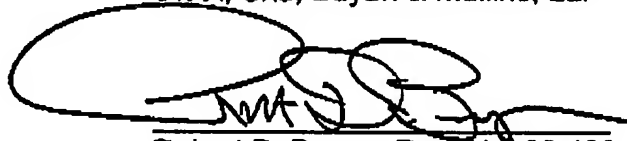
☐ Check No. \_\_\_\_\_ is enclosed covering the additional filing fees in the amount of \$ \_\_\_\_\_. This check covers the required extension of time fee of \$ \_\_\_\_\_. No additional claim fee is seen to be due based on the following calculation:

	(Col. 1) No. Filed	(Col. 2) No. extra	Small Entity			Other than Small Entity	
For			Rate	Fee	or	Rate	Fee
Basic fee				\$150	or		\$300
Examination fee				\$100	or		\$200
Search Fee				\$250	or		\$500
Total claims	20 - 20=	0	x 25	\$ 80	or	x 50	\$ 0
Indep claims	3 - 3=	0	x 100	\$ 0	or	x 200	\$ 0
Multiple dependent claims presented			+ 180	\$	or	+ 360	\$
			Total	\$ 0	or	Total	\$ 0

☒ The Commissioner is hereby authorized to charge any underpayment or credit any overpayment of the filing fees required under 37 CFR §1.16 and any patent application processing fees required under 37 §CFR 1.17 to Deposit Account No. 50-0878.

Respectfully submitted,

Stout, Uxa, Buyan & Mullins, LLP



Robert D. Buyan, Reg. No. 32,460

Date: October 2, 2006

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OCT 02 2006

Atty. Docket No. UCIVN-058C

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Meyskens )  
Application No.: 10/780,921 )  
Filed: 02/17/2004 )  
For: Alpha-Difluoromethylornithine )  
(DFMO) Suppresses Polyamine )  
Levels in the Human Prostate )

Art Unit: 1614

Examiner: Anderson, James D.

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Commissioner for Patents, P.O. Box 1450, Alexandria,  
VA 22313-1450 on Oct 1 2006

By: 

Nancy V. McElrath

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed June 2, 2006, Applicant provisionally elects to prosecute Group IV (claims 84-87), with traverse.

Applicant respectfully traverses the restriction requirement on grounds that Group IV (claims 84-87) should be combined with Group V (claims 88-95) such that Group IV should include all of claims 84-95.

The claims of Group IV are directed to a method for treating benign prostatic hyperplasia (BPH) comprising the administration of DFMO to a subject. On the other

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Amendment  
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hand, the claims of Group V are directed to a method for treating BPH comprising the administration of DFMO and a second therapeutic agent to a subject.

At page 5 of the Office Action, it is recognized that the claims of Groups IV and V-VI are directed to related methods for treating BPH. However, in support of the restriction requirement, the Examiner contends that the related methods of Groups IV and V do no overlap in scope and are thus patentably distinct. Applicant respectfully disagrees with this conclusion, at least with respect to Groups IV and V.

It must be noted that the claims of Group V are open ended (i.e., they use the term "comprising") and, thus, do not preclude the co-administration of other therapeutic agents in addition to DFMO. In fact, independent claim 84 reads literally on each of the claims in Group IV (i.e., claims 88-95). Thus, the claims of Group IV clearly do overlap with the claims of Group V. Moreover, the "second" therapeutic agents recited in Group V claims are limited to alpha-1 adrenergic blockers and 5-alpha-reductase enzyme blockers, both of which are categories of agents that are previously known for use in treating BPH.

In view of the foregoing facts, Applicant respectfully submits that combining the claims of Group V with those of provisionally elected Group IV will not place any undue burden on the Examiner and will facilitate expeditious prosecution of this application. Accordingly, it is hereby requested that Groups IV and V be combined and that examination proceed on claims 84-95.

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Amendment  
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The Examiner is invited to telephone Applicant's undersigned counsel to discuss this response or any further measures that may be taken to facilitate issuance of a Notice of Allowance on this application.

Respectfully submitted,  
STOUT, UXA, BUYAN & MULLINS, LLP

Date: October 1, 2006

  
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